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| 10/604,944      | 08/28/2003  | Itzhak Bentwich      | 06087.0300.CPUS08   | 1943             |

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EXAMINER

DEJONG, ERIC S

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1631

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/604,944

Applicant(s)

BENTWICH, ITZHAK

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-25 is/are pending in the application.
- 4a) Of the above claim(s) 2,5-7,9,10,13,15-22,24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,11,12,14 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 2,5-7,9,21,22,24 and 25 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED OFFICE ACTION

### *Election/Restrictions*

Applicant's election with traverse of SEQ ID No. 14 in the reply filed on 12/15/2005 is acknowledged. The traversal is on the grounds that the examiner has failed to demonstrate that the claimed sequences are an exceptional case necessitating the number of sequences be less than 10 and that applicants.

The MPEP § 803.04 states:

"By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode different proteins are structurally distinct chemical compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together."

In regards to the determination of a reasonable number of sequences for examination, it is stated that in most cases up to ten independent and distinct sequences may be examined in without restriction. The requirement for an election of a single disclosed sequence is consonant with the guidance provided by the above citation from the MPEP, as one sequence is within the provided range of up to ten independent or distinct sequences. There is no support in the cited portions of the MPEP requiring an examiner to demonstrate that the claimed sequences are an exceptional case regarding a restriction requirement to independent and distinct sequences. Therefore applicants arguments are not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Amended claims 2, 5-7, 21, 22, 24 and 25 now drawn to isolated RNA sequences, as well as the compliments thereof, encoded by SEQ ID No. 14. These newly recited RNA sequences are presumed to represent independent and distinct inventions from that of the elected sequence, SEQ ID No. 14, as applicants response does not provide evidence to the contrary. Therefore, claims 2, 5-7, 21, 22, 24 and 25 are not found to be drawn to the elected invention.

Claims 2, 5-7, 9, 10, 13, 15-20, 21, 22, 24, and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 12/15/2005.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. See for example paragraphs [0401]-[1031]. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Double Patenting***

Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In *re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In *re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an

obvious variation of a claim,” but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

Claims 1, 8, 11, 12, 14, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12, and 14 of copending Application No. 10/605,838; claims 1-8, 12, and 15 of copending Application No. 10/605,840; claims 1-8, 12, and 14 of copending Application No. 10/707,003; claims 1, 2, and 4 of copending Application No. 10/708,952; and claims 1, 2, and 5 of copending Application No. 10/709,739. Although the conflicting claims are not identical, they are not patentably distinct from each other because the identified claims in the above copending applications are generically drawn to a plurality of sequences that are provided for in their respective disclosures. Since the above identified copending applications are related as child applications of the instant application (parent), the nucleotide sequences disclosed therein encompass SEQ ID No. 14 as is claimed in the instant application. Therefore the instant claims, which are specific to

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SEQ ID No. 14, are encompassed by the more broadly drawn claims of the above identified copending applications encompass a plurality of disclosed sequences.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants are further reminded of their duty to disclose information regarding any copending or related applications that contain claims drawn to nucleic acid sequences and wherein the respective disclosure includes a listing of SEQ ID No 14. as listed in the instant application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 11, 12, 14, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Brander et al.

The claims are drawn to an isolated nucleic acid comprising the sequence of SEQ ID No. 14, a vector comprising SEQ ID No. 14, a means for inserting said vector into a cell, a probe comprising SEQ ID No. 14, a gene expression diction system comprising the probe comprising SEQ ID No. 14, and an isolated nucleic acid complementary to the nucleic acid comprising SEQ ID No. 14.

[Claims 1 and 23]: Brander et al. disclose the isolation of the and HIV-1 viral sequence for the Gag p17 region (gag) gene, and the subsequent submission to Genbank under accession number AF017925, which has 100% identity to that of the elected sequence, SEQ ID No. 14 (see Brander et al., page 2560, col. 2., lines 38-46) and a nucleic acid complementary to a nucleic acid comprising SEQ ID No. 14.

[Claims 8, 11, and 12]: Brander et al. further discloses that the identified gag genes were isolated using routine molecular cloning techniques relying on PCR and cell transformations involving vector constructs containing the disclosed sequences (see Brander et al. pg 2560, col. 1, line 5 through col. 2, line 37), which reads on the instantly claimed limitations drawn to a vector, and a probe comprising SEQ ID No. 14, as well as a means for inserting said vector into a cell.

[Claim 14]: Brander et al. further sets forth that the identified HIV-1 gag sequences were relied upon in a quantitative analysis of the expression of HIV-1 gag protein and variants thereof in HIV-1 cell lines (see page 2560, col. 2, line 48 through page 2564, col. 1, line 25), which reads upon the instantly claimed gene expression detection system comprising a probe comprising SEQ ID No. 14 and a gene expression detector.



### ***Conclusion***

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

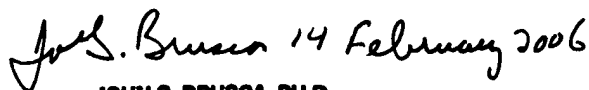
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EDJ



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**PRIMARY EXAMINER**